



March 27, 1997

COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

Re:

U.S. Application Serial No.: 08/517,901

Title: Wound Therapy Device and Related Methods

Docket No.: 06 2916.312

Dear Sir:

Enclosed herewith for filing in the above-referenced matter are the following:

- 1. Information Disclosure Statement;
- 2. Form PTO-1449;
- 3. Check in the amount of \$230; and
- 4. An acknowledgment postcard.

The Commissioner is hereby authorized to charge any additional fees which may be required to Deposit Account No. 01-0477. A duplicate copy of this transmittal letter is enclosed.

Respectfully submitted,

KINETIC CONCEPTS, INC.

By:

William H. Quirk, IV

Reg. No. 33,996

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Cesar Z. Lina, et al. Attorney Docket No: 06 2916.312 Assignee: Kinetic Concepts, Inc. Examiner: D. Ruhl. 330 GL 04/11/97 08517901 1 126 230.00 CK Serial No: 08/517,901 Group Art Unit: 3308 Filed: August 22, 1995 Title: WOUND THERAPY DEVICE

INFORMATION DISCLOSURE STATEMENT

COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

AND RELATED METHODS

RECEIVED

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Sir:

GROUP 3300

In compliance with Applicant's duty of candor and good faith, under 37 C.F.R. § 1.56, the Examiner is requested to consider the following references and related information submitted in accordance with 37 C.F.R. § 1.97, and thereafter make this entire disclosure "of record" in the above-captioned application. Although disclosed, nothing herein is intended as an admission of "the character of any reference as "prior art" to the invention of the above-captioned application or as being material to the examination of the same. Under no circumstance does disclosure herein imply materiality to patentability as defined in 37 C.F.R. § 1.56(b).

U.S. Patent No. 3,026,874 issued to Stevens March 27, 1962 generally discloses a wound shield for surgically or otherwise produced surface wounds. The stated primary object of the invention is to provide an efficient and versatile device that enables and facilitates controlled drainage of a wound. According to the disclosure, vacuum, gravity or medication may be applied to an unbandaged wound along with controlled admission or exclusion of air from the wound. The device is said to surround and isolate the wound, while avoiding contact with the wound, and is further said to afford free visual inspection of the wound.

U.S. Patent No. 3,804,090 issued to Holbrook April 16, 1974 generally discloses a structure providing for the addition of a foam reducing additive into the body-fluid flow of a sealed, self-contained, vacuum operated aspiration system. The customary vacuum bottle is supplied, proximate its fluid inlet, with an additive connection or structure communicating with the interior of the liquid feed-in line such that as liquid is drawn in under the influence of a reduced pressure within the vacuum bottle, the additive will likewise be drawn in, generally in proportional amounts. Many embodiments are suggested such as an additive bottle connection leading to a coupling elbow, an additive bottle teed into the body-fluid line, an additive bottle including a line-puncture cannula needle, and so forth. By the structure, either atmospheric pressure directly on the additive liquid or on the sides of a collapsible container thereof is relied upon to produce the pressure necessary to introduce and sustain introduction of additive into the feed-in line.

U.S. Patent No. 4,382,441 issued to Svedman May 10, 1983 discloses a device useful in treating tissues generally comprising a dressing made from a porous material. The dressing is intended for placing against tissues such as skin. The material is disclosed as being synthetic or organic and is distinguished by communicating cavities in the form of open pores, interdigitating gaps in particle material or communicating cavities in capillary structures. According to the disclosure, a fluid supply and/or removal channel could be effected under pressure and/or suction, respectively.

U.S. Patent No. 4,460,361 issued to Nichols July 17, 1984 generally discloses a purportedly improved vacuum attachment assembly for suction apparatus. The invention includes a vacuum line coupling system that is incompatible with the inlet port such that inadvertent attachment of the vacuum line to the inlet port is impossible. The vacuum connection system further includes a permanently attached tee and vacuum leader line for parallel connection of the vacuum source to the interior and exterior of a liner disposed within the apparatus. The improved vacuum attachment system is said to allow easy disconnection and reconnection of the vacuum source.

U.S. Patent No. 4,540,412 issued to Van Overloop September 10, 1985 generally discloses an apparatus useful in providing patient therapy through the use of wet dressings. The apparatus comprises a device for generating heated moist air and a sheet of substantially air impervious material to cover the wet dressing. Spaced portions of the sheet are secured to the

patient. The generating device is coupled to the inside of the sheet intermediate the sheet and the patient to permit passage of the heated moist air onto the wet dressing.

U.S. Patent No. 4,605,400 issued to Kurtz et al. August 12, 1986 generally discloses a surgical pleural drainage apparatus for draining fluids from the body of a patient. The apparatus includes a container with a collection chamber. A suction outlet is provided and connected, through a fluid passageway, to the container. The suction outlet is further connected to a source of negative pressure. A non-liquid one-way valve is provided in the fluid passageway for allowing fluid flow only from the collection chamber to the suction outlet. An air leak indicator is also provided in the passageway to indicate a flow of gases through the passageway and optionally the qualitative quantity of that flow. Preferably, the air leak indicator includes a visible liquid trap through which any gases flow and form bubbles, which are visible. The liquid trap is pre-filled with glycerine or a like liquid. A suction control device determines the amount of negative pressure applied to the collection chamber. A negative pressure relief device and a positive pressure relief device are also provided for the collection chamber. Preferably, a pressure-measuring device is provided for measuring the pressure in the passageway and a dynamic pressure-measuring device is provided for measuring the pressure changes in the collection chamber during respiration.

U.S. Patent No. 4,631,061 issued to Martin December 23, 1986 discloses an automatic urine detecting, collecting and storing device generally comprising a shallow collection vessel with liquid sensors and a resilient lip which allows air around the genital-urinary area when not activated. Liquid urine in the vessel causes sensors to activate a vacuum pump drawing the lip against the body of the user for a liquid tight seal and pumping of urine from the vessel through a tube and one-way valve to a temporary storage tank. Close and random spacing of the sensors creates a very sensitive device activated when the device is in any orientation that may cause some minimal amount of urine to contact the body. This is said to allow the vacuum pump to remain active, evaporating the urine within the vessel until the vessel is substantially dry. Paired electrical contacts or paired fiber optic elements may be alternatively used as liquid sensor means. Liquid level indicators within the tank signal a desired level for emptying and cause the pump to shut off upon reaching a dangerously full level. A condensation collection trap keeps liquid out of the pump. A charcoal filter prevents urine odor from entering the atmosphere and reduces the vacuum

pump noise exiting to the outside. A quick release valve is used to empty the tank. Working elements are housed in a sound insulated enclosure, which may be a simulated carrying case or backpack for ease of mobility. Variable self-contained and remote power sources may be used.

U.S. Patent 4,969,880 issued to Zamierowski November 13, 1990 discloses a wound dressing and treatment method generally comprising a cover membrane including a semi-permeable material having an adhesive-coated skin contact surface. An opening is formed in an interior portion of the membrane. An intermediate layer of material may be placed between the wound and the membrane contact surface for either absorbing fluids from the wound, or for passing such fluids to the opening with a synthetic material. A tube includes a proximate end in fluid communication with the wound through the membrane opening. A distal end of the tube is adapted for connection to a suction source for draining the wound or to a fluid source for introducing liquid medication to the wound. According to the disclosure, both evacuation and introduction can be either active or passive.

U.S. Patent No. 5,149,331 issued to Ferdman *et al.* September 22, 1992 discloses a method and device, generally utilizing a porous, adhesive backed dressing, useful for wound closure. A vacuum and/or heat is applied to the wound site through the dressing so as to draw the tissue adjacent the wound site to the dressing. It is said that this method minimizes trauma to the wound and increases the adherence of the adhesive.

U.S. Patent No. 5,234,419 issued to Bryant et al. August 10, 1993 discloses a suction drainage infection control system that purportedly reduces an operator's exposure to infectious waste by permitting waste-treating material to be dispersed into a sealed chamber in which the infectious waste is contained. The sealed chamber generally includes a cover with a flexible liner sealed to and suspended therefrom. A freely movable reservoir is provided inside the sealed chamber for storing the waste-treating material. According to the disclosure, the reservoir may be opened by manipulation of the flexible liner.

E.P.O. Patent Application 0 358 302 published March 14, 1990 generally discloses a medico-surgical suction container having a suction inlet connected to a suction catheter and an outlet connected to a vacuum pump. In particular, the application further discloses hydrophobic filter means interposed between the outlet and vacuum pump. The filter generally comprises a

layer of a PTFE membrane on a support screen and a layer of a glass microfiber laminated to a polymer monofilament.

German Patent No. 28 09 828 published September 21, 1978 appears to be written in the German language. Although Applicant is not believed to be possessed of a translation, and can therefore only speculate as to relevance, particular reference to the accompanying figures discloses what may be some sort of wound dressing having fluid inlet and outlet means.

P.C.T. Application No. WO 93/09727 published May 27, 1993 discloses a method and apparatus for treating tissue damage generally comprising a vacuum means for creating a negative pressure on a tissue area surrounding a wound, a sealing means operatively associated with the vacuum means for maintaining negative pressure on the wound and a screen means for preventing overgrowth of tissue in the area of the wound. Specifically, the application discloses the use of an open-cell foam for application over the wound. The foam is provided with a tube for attachment to a suction pump. The tube and foam are covered by flexible polymer sheet configured to be adhered to the skin surrounding the wound.

P.C.T. Application No. WO 93/09736 published May 27, 1993 discloses an apparatus useful in the management of urinary incontinence. The apparatus generally comprises a vacuum pump and collection reservoir in fluid communication with a pad which is specially designed to wick liquid away from the volume of the pad and toward a centrally provided perforated tube. This tube then provides the fluid communication with the suction and collection apparatus.

All of the references herein above disclosed are in general believed to be related at least to the broad field of art to which the invention of the present application pertains although some references are more relevant than others. It is quite possible, however, that Applicant's view is tainted by hindsight as all of these references were considered only after completion of Applicant's invention, wherein said invention may serve to guide one to seeing relevance that one of ordinary skill in the art may otherwise not see. Although disclosed, nothing herein is intended as an admission of the character of any reference as "prior art" to the invention of the above-captioned application. In any case, Applicant respectfully requests the Examiner make careful consideration of all that is disclosed herein for whatever relevance may actually exist.

In light of all the foregoing, Applicant respectfully requests reconsideration and allowance of the claims and passage to issue of this present application with this disclosure a matter of record. A Form PTO-1449 is provided for the Examiner's convenience.

Respectfully submitted,

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